

PATENT**CERTIFICATE OF MAILING**

I hereby certify that on August 10, 2001, this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, DC 20231.

37 C.F.R. § 1.8(a)
 with sufficient postage
as first class mail

37 C.F.R. § 1.10
 as "Express Mail Post Office to
Addressee" Mailing Label No.

Jessica Brown



Applicant:

Wesley Paul Durkalski

09/836,653

April 17, 2001

**SYSTEM AND METHOD FOR
ENABLING AN UNTRAINED OR
NOVICE END-USER TO RAPIDLY
BUILD CLINICAL TRIALS DATA
MANAGEMENT SYSTEMS**

**COMPLIANT WITH ALL
APPROPRIATE REGULATORY
GUIDANCES**

Examiner:

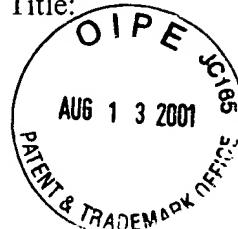
Not Yet Assigned

Group Art Unit:

2171

Atty. Docket No.:

20207-11

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE****RESPONSE TO NOTICE TO FILE CORRECTED APPLICATION PAPERS, MAILED JUNE 12, 2001**

Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Notice to file Corrected Application Papers, mailed June 12, 2001, Applicant has prepared corrected drawings sheets in compliance with 37 CFR 1.84. Accordingly, Applicant submits the following papers:

- This Response to Notice to File Corrected Application Papers;
- A Copy of the Notice to File Corrected Application Papers, Part 2;
- The Application filed April 17, 2001, including Ten (10) Replacement Drawing Sheets (Figs. 1-10).

Additionally, Applicant submits for consideration in this case:

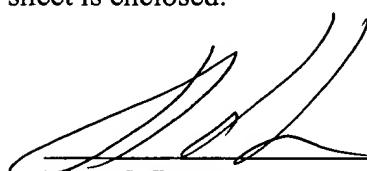
- Request for Corrected Filing Receipt;
- Information Disclosure Statement;
- Form PTO-1449 with copies of cited references; and
- Return acknowledgement postcard.

Applicant: Wesley Paul Durka
Serial No.: 09/836,653
Group Art Unit: 2171

PATENT
Attorney Docket: 20207-11

Please charge any fees associated with this filing or credit overpayment to Deposit
Account No. 16-2230. A duplicate of this sheet is enclosed.

Dated: August 10, 2001



Marc E. Brown
Reg. No. 28,590

OPPENHEIMER WOLFF & DONNELLY LLP
2029 Century Park East, 38th Floor
Los Angeles, California 90067-3024
Telephone: 310.788.5000
Fax: 310.788.5100

AA
I CERTIFY THAT ON AUGUST 10, 2001, WHICH IS THE DATE I AM SIGNING THIS CERTIFICATE, THIS CORRESPONDENCE AND IDENTIFIED ENCLUSES ARE BEING DEPOSITED IN THE UNITED STATES POSTAL SERVICE, POSTAGE PAID FIRST CLASS, IN AN ENVELOPE ADDRESSED TO: COMMISSIONER OF PATENTS AND TRADEMARKS, WASHINGTON, D.C. 20231.



Receipt
ffy
PATENT
Docket No. 20207-11

JESSICA BROWN

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Wesley Paul Durkalski

For: System and Method for Enabling an Untrained or Novice End-User to Rapidly Build Clinical Trials Data Management Systems Compliant With All Appropriate Regulatory Guidelines

Serial No.: 09/836,653

Filed: April 17, 2001

REQUEST FOR CORRECTED FILING RECEIPT

Commissioner for Patents
Office of Initial Patent Examination
Customer Service Center
Washington, D.C. 20231

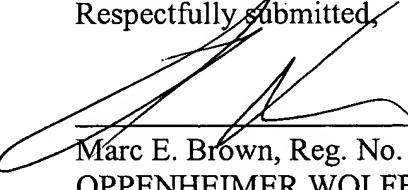
Sir:

1. Attached is a copy of the official filing receipt received from the Patent & Trademark Office in the above application for which issuance of a corrected filing receipt is respectfully requested.

2. There is an error in title of the invention. The word "cilihanical" should be changed to "clinical" as follows: "Systems and methods for enabling an untrained or novice end-user to rapidly build clinical trials data management systems compliant with all appropriate regulatory guidances."

Respectfully submitted,

Dated: August 10, 2001


Marc E. Brown, Reg. No. 28,590
OPPENHEIMER WOLFF & DONNELLY LLP
2029 Century Park East, 38th Floor
Los Angeles, California 90067-3024
Phone: (310) 788-5000 * Fax: (310) 788-5100



UNITED STATES PATENT AND TRADEMARK OFFICE

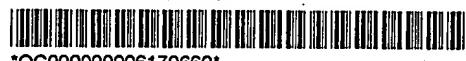
O I P E
AUG 13 2001

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
09/836,653	04/17/2001	2171	395	20207-11	10	20	4

CONFIRMATION NO. 7384

FILING RECEIPT



OC000000006170660

OPPAENHEIMER WOLFF & DONNELLY LLP
ATTN: MARC E. BROWN, ESQ.
38TH FLOOR
2029 CENTURY PARK EAST
LOS ANGELES, CA 90067

Date Mailed: 06/12/2001

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Wesley Paul Durkalski, Charleston, SC;

Domestic Priority data as claimed by applicant

THIS APPLN CLAIMS BENEFIT OF 60/197,648 04/17/2000

DOCKETED

Foreign Applications

JUN 15 2001

If Required, Foreign Filing License Granted 06/11/2001

OWD-LA

Projected Publication Date: To Be Determined - pending completion of Corrected Papers

Non-Publication Request: No

OWD

Early Publication Request: No

JUN 15 2001

**** SMALL ENTITY ****

RECEIVED
clinical

Title

Systems and methods for enabling an untrained or novice end-user to rapidly build *clinical* trials data management systems compliant with all appropriate regulatory guidances

Preliminary Class

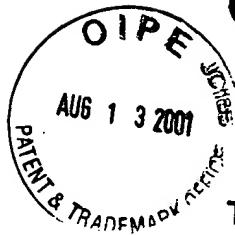
707

Data entry by : DUONG, MICHAEL

Team : OIPE

Date: 06/12/2001





**LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15**

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Office of Export Administration, Department of Commerce (15 CFR 370.10 (j)); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

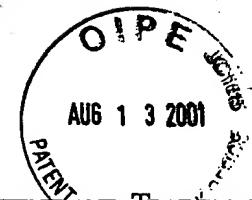
No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15 (b).

PLEASE NOTE the following information about the Filing Receipt:

- The articles such as "a," "an" and "the" are not included as the first words in the title of an application. They are considered to be unnecessary to the understanding of the title.
- The words "new," "improved," "improvements in" or "relating to" are not included as first words in the title of an application because a patent application, by nature, is a new idea or improvement.
- The title may be truncated if it consists of more than 500 characters (letters and spaces combined).
- The docket number allows a maximum of 25 characters.
- If your application was submitted under 37 CFR 1.10, your filing date should be the "date in" found on the Express Mail label. If there is a discrepancy, you should submit a request for a corrected Filing Receipt along with a copy of the Express Mail label showing the "date in."
- The title is recorded in sentence case.

Any corrections that may need to be done to your Filing Receipt should be directed to:

Assistant Commissioner for Patents
Office of Initial Patent Examination
Customer Service Center
Washington, DC 20231



UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
09/836,653	04/17/2001	Wesley Paul Durkalski	20207-11

CONFIRMATION NO. 7384

FORMALITIES LETTER



OC00000006170661

OPPAENHEIMER WOLFF & DONNELLY LLP
ATTN: MARC E. BROWN, ESQ.
38TH FLOOR
2029 CENTURY PARK EAST
LOS ANGELES, CA 90067

Date Mailed: 06/12/2001

FILING DATE GRANTED

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Filing Date Granted

This application has been accorded an Application Number and Filing Date. The application, however, is informal since it does not comply with the regulations for the reason(s) indicated below. Applicant is given **TWO MONTHS** from the date of this Notice within which to correct the informalities indicated below. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a)

The required item(s) identified below must be timely submitted to avoid abandonment:

- Substitute drawings in compliance with 37 CFR 1.84 because:

- drawing sheets do not have the appropriate margin(s) (see 37 CFR 1.84(g)). Each sheet must include a top margin of at least 2.5 cm. (1 inch), a left side margin of at least 2.5 cm. (1 inch), a right side margin of at least 1.5 cm. (5/8 inch), and a bottom margin of at least 1.0 cm. (3/8 inch);

*A copy of this notice **MUST** be returned with the reply.*

MDmng

Customer Service Center

Initial Patent Examination Division (703) 308-1202

PART 2 - COPY TO BE RETURNED WITH RESPONSE